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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/928,272	09/12/1997	MICHAEL J. ISKRA	P-3818	9434
7590 RICHARD J RODRICK BECTON DICKINSON AND COMPANY 1 BECTON DRIVE FRANKLIN LAKES, NJ 074171880			EXAMINER MATTER, KRISTEN CLARETTE	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 05/07/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

08/928,272

**Applicant(s)**

ISKRA, MICHAEL J.

**Examiner**

KRISTEN C. MATTER

**Art Unit**

3771

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### **DETAILED ACTION**

This Action is in response to the amendment filed on 4/15/09. No claims have been amended, added or cancelled. Therefore, claims 1 and 5-9 are currently pending in the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1 and 5- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns (US 5,458,854) in view of Arlman (US 3,918,909).**

Regarding claim 1, Burns discloses a one piece collection container assembly comprising an elongate tubular housing (12) having opposed first and second ends (see Figure 2), a solid partition (38) contacting a sidewall (22) of the tube forming a closed bottom (38) and positioned within said housing between the first and second ends (see Figure 2), said housing defining a volume for specimen collection and containment therein between said first end and said partition (see abstract), said second end forming a false bottom comprising a bottom end below said partition comprising an annular skirt (37) comprising an opening (47) therein.

The sole difference between Burns and the instant invention is the bottom of the tube being semi-spherical. However, absent a critical teaching and/or a showing of unexpected results from the tube having a semi-spherical bottom examiner contends that such a modification is an

obvious design consideration to one of ordinary skill in the art as a mere change in shape that does not patentably distinguish an invention over the prior art. Changing the bottom to a semi-spherical shape would allow the tube to be compatible with common standard clinical equipment and instrumentation depending on the exact intended use of the tube. In addition, Arlman teaches a specimen collection tube with a false bottom surface (2) having a semi-spherical shape (see Figures 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Burns device with a semi-spherical false bottom as taught by Arlman depending on the intended use of the device or to allow compatibility with standard clinical equipment because such a shape was well known at the time of the invention. Such a modification would involve substitution of a well known method (semi-spherical bottom) into a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claim 5, the partition disclosed by Burns is arcuate in shape and has at least a partially rounded bottom portion (see Figure 2).

Regarding claim 6, Burns lacks the partition being conical. However, absent a critical teaching and/or a showing of unexpected results from the partition being conical (as opposed to arcuate), examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape without a change in function that does not patentably distinguish an invention over the prior art. Furthermore, it appears as though the tube of Burns would work equally well with any shape of partition so long as specimen could be retained.

Regarding claims 7 and 8, Burns discloses the housing can be made of a thermoplastic polymer such as polyvinyl chloride (column 5, lines 43-50).

Regarding claim 9, Burns is silent as to the dimensions of the container. However, absent a critical teaching and/or showing of unexpected results from making the container the claimed dimensions, examiner contends that it is an obvious design consideration to one of ordinary skill in the art to make the Burns container the claimed dimensions because those dimensions are commonly used for blood/specimen collection containers. In addition, it appears as though the device of Burns would perform equally well with the claimed dimensions. See also *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), in which the court held that mere changes in size do not patentably distinguish an invention over the prior art.

### ***Response to Arguments***

Applicant's arguments filed 4/15/2010 have been fully considered but they are not persuasive.

In response to applicant's argument that one would not modify the shape of Burns because the cap of Burns would then to be able to be placed onto the bottom of the tube to allow it to stand upright, examiner maintains that depending on the exact use of the device and available equipment to a user, the shape of the bottom of Burns tube is an obvious design consideration. For example, there are standard centrifuges and tube holders that would allow the tube to stand upright even with a semi-spherical false bottom, which would allow the device to perform equally well as if set on a flat surface. In fact, having the tube be semi-spherical to insert into such standard devices would provide the advantage of having Burn's tube be more stable

when upright and unsupported by a user so that the tube would be less likely to tip over if the flat surface were bumped, for example. Therefore, changing the bottom surface shape of Burns does not destroy the reference, because the device would perform equally well with any shaped bottom that would have allowed the device to maintain an upright position (with or without a standard stand), and is considered an obvious design consideration to one of ordinary skill in the art.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, as discussed above, changing the shape of Burns from a well known tube to a well known semi-spherical bottom is an obvious design consideration involving a mere change in shape that does not patentably distinguish an invention over the prior art.

Additionally, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). *Arlman* is cited merely to show that at the time the invention was made, tubes having open ended (i.e., false-bottom) bottoms with a semi-spherical shape were well known and commonly used in the art. Thus, whether

Arlman has a structure that can be called "the false bottom" for reading on the instant claim language in combination with the other claim limitations (or the intended proposed use such as for connection to standard equipment) is not relevant to the instant rejection because only the shape of Arlman's bottom surface is being relied on in the rejection and common sense allows one to conclude that the semi-spherical bottom is compatible with standard laboratory equipment.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/  
Primary Examiner, Art Unit 3771

/Kristen C. Matter/  
Examiner, Art Unit 3771